

## REMARKS

Claims 1-65 are pending in this application. Claims 1-61 and new claims 62-65 are presented for the Examiner's review and consideration. No new matter has been added, as the new claims are supported by the specification as originally filed. Applicants acknowledge the Examiner's statement that claims 53 and 54 contain allowable subject matter.

In the Office Action, Claims 1-52 and 55-61 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,466,237 to Byrd, III *et al.* ("the Byrd") in view of U.S. Patent No. 5,562,663 to Wisniewski *et al.* ("Wisniewski"). The Examiner stated in part:

"Byrd, III *et al.* disclose a bone fixation device 10 comprising a bone fastener 15, a receiving member 14, a longitudinal support member 20 passing through a transverse channel 17 in the receiving member, and a threaded clamping member 25, which positively locks the fastener in a selectable angular position relative to the receiving member. The fastener includes a semi-spherical head 48 and an integral shank 15 and collar 40. The head includes a knurled surface 43 to increase friction and create a positive lock between the head and the receiving member. Byrd, III *et al.* do not disclose the concentric edges about the spherical head. Wisniewski *et al.* teach, in a similar device, that sharp ridges, knurled surfaces, and diamond embossed surfaces are functionally equivalent means of increasing interface friction, known in the art at the time of the invention (see Figs 2, 18, and 19, col. 3, lines 32-34, col. 5, lines 13-15, and col. 6, lines 37-44, 64, and 65). Therefore, it would have been obvious to a person of ordinary skill to substitute a series of ridges or a diamond embossed surface for a knurled surface, this being merely the substitution of functionally equivalent means of increasing interface friction, known in the art. The series of ridges necessarily have different diameters along the different locations on the semi-spherical head."

(Office Action mailed 7/30/2003, page 2, line 15 to page 3, line 5).

Independent claim 1 recites, *inter alia*, "a bone fastener comprising a head, a shank, and a collar, the collar having a top portion and a plurality of lower portions, at least two adjacent lower portions forming at least one edge, wherein the collar and inner surface contact one another along the at least one edge."

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness in rejecting claim 1. MPEP Section 2143.03 states:

"To establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is non obvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

In rejecting claim 1, the Examiner has not met his burden of applying the cited references to each and every element of the claim. In particular, the Examiner has not identified the features of the cited references which purportedly correspond to “a plurality of lower portions, at least two adjacent lower portions forming at least one edge, wherein the collar and inner surface contact one another along the at least one edge.” Applicants, therefore, submit that the Examiner has not explained with reasonable specificity the statement of rejection with regard to all limitations in claim 1, and thus has procedurally failed to establish a *prima facie* case of obviousness for claim 1.

With respect to claims 2-25, which depend from claim 1, Applicants submit that, because independent claim 1 is nonobvious under 35 U.S.C. 103 due to the failure to state a *prima facie* case, then any claim depending therefrom is non obvious.

Independent claim 26 recites, *inter alia*, “a bone fastener comprising a collar and a shank, the collar having a top portion and a plurality of lower portions, at least two adjacent lower portions forming at least one edge.” For the reasons, stated above with respect to claim 1, Applicants submit that the Examiner has not met his burden of applying the cited references to each and every element of claim 26. In particular, the Examiner has not identified the features of the cited references which purportedly correspond to “a plurality of lower portions, at least two adjacent lower portions forming at least one edge, wherein the collar and inner surface contact one another along the at least one edge.” Applicants, therefore, submit that the Examiner has not explained with reasonable specificity the statement of rejection with regard to all limitations in claim 26, and thus has procedurally failed to establish a *prima facie* case of obviousness for claim 26.

With respect to claims 27-42, which depend from claim 1, Applicants submit that, because independent claim 1 is nonobvious under 35 U.S.C. 103 due to the failure to state a *prima facie* case, then any claim depending therefrom is non obvious.

Independent claim 43 recites, *inter alia*, “a head, a shank, and a collar disposed between the head and shank and comprising a top portion and a plurality of lower portions, at least two adjacent lower portions forming at least one edge generally concentric to a longitudinal axis of the bone screw.” For the reasons, stated above with respect to claim 1, Applicants submit that the Examiner has not met his burden of applying the cited references to each and every element of claim 43. In particular, the Examiner has not identified the features of the cited references which purportedly correspond to “a collar disposed between the head and shank and comprising a top portion and a plurality of lower

portions, at least two adjacent lower portions forming at least one edge generally concentric to a longitudinal axis of the bone screw.” Applicants, therefore, submit that the Examiner has not explained with reasonable specificity the statement of rejection with regard to all limitations in claim 43, and thus has procedurally failed to establish a *prima facie* case of obviousness for claim 43.

With respect to claims 44-61, which depend from claim 43, Applicants submit that, because independent claim 1 is nonobvious under 35 U.S.C. 103 due to the failure to state a *prima facie* case, then any claim depending therefrom is non obvious.

Moreover, applicants submit there is no suggestion or motivation in the references to modify or combine the reference teachings as stated by the Examiner. For instance, Byrd discloses a bone interface anchor for holding a stabilization rod . (Byrd, 1:6-8). The anchor can be adjusted after implantation to receive a stabilizer, and is locked into position after assembly. (*Id.*, 8-10). Byrd states: “A preferred method of achieving the locking engagement is to provide a knurling on the bottom side of the bone screw, and on the inside surface of the seat screw socket.” (*Id.*, 2:8-11). Byrd teaches away from providing a “series of ridges or a diamond embossed surface for a knurled surface,” because a knurled surface is preferred by Byrd. As there is no teaching or suggestion in Byrd for the need for or utility of a “series of ridges or a diamond embossed surface” in association with the assembly of Byrd, the combination of Byrd with Wisnewski is not appropriate.

Furthermore, even if one were to provide “a series of ridges or a diamond embossed surface for a knurled surface,” as stated by the Examiner, there is no suggestion in the prior art of the desirability of making them “concentric edges about the spherical head.” The Examiner’s statement that “[t]he series of ridges necessarily have different diameters along the different locations on the semi-spherical head,” is also not appropriate for the same reason. The combination of Byrd with Wisnewski, therefore, constitutes a hindsight reconstruction of the subject matter of the claims, using applicants’ invention as the blue print.

For these reasons, Applicants respectfully submit that the rejections of claims 1-52 and 55-61 under 35 U.S.C. 103(a) have been overcome and should be withdrawn.

New independent claim 62 recites, *inter alia*, features of a bone fastener comprising a head, a shank, and a collar, the collar having a top portion and a plurality of lower portions, at least two adjacent lower portions forming at least one circular edge. Claim 62 further defines over Byrd and Wisnewski, for example, by reciting a collar having “a plurality of lower portions, at least two adjacent lower portions forming at least one circular

edge.” Claims 63-65 depend from claim 62 and recite additional features of the fixation assembly. These claims are believed to be patentable over Byrd and Wisneski for the same reasons as claim 62, as well as the additional features recited in claims 63-65.

In view of the foregoing, it is submitted that all rejections have been overcome and should be withdrawn, and all claims are in condition for allowance. Reconsideration of the application in view of the foregoing remarks is respectfully requested. The Examiner is invited to call the undersigned if a telephone call could help resolve any remaining items.

Applicants believe that fees are due in connection with the submission of this amendment as calculated on the attached Fee Transmittal Sheet. Should any other fees be required, however, please charge all required fees under 37 C.F.R. 1.17 to Pennie & Edmonds Deposit Account No. 16-1150.

Respectfully submitted,



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